

REMARKS

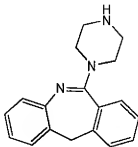
No amendments are made herein. Claims 1-9 and 59-101 are pending. Claims 82-101 were previously presented in the Amendment to Copy Claims filed by Applicants on October 18, 2007, which were filed in order to present claims that are copied in significant part from U.S. Application No. 10/545,767. Claims 59 and 61-64 stand withdrawn. Applicants reserve all rights of rejoinder of the withdrawn claims.

In their January 22, 2008 response, Applicants mistakenly depicted the structure of N-desmethyloclozapine as an azepine instead of a diazepine. The structure of N-desmethyloclozapine as depicted below has been corrected.

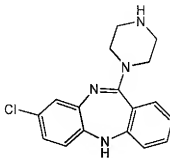
Applicants have carefully considered all of the Examiner's rejections but respectfully submit that the claims are allowable for at least the following reasons.

Rejections under § 103

The Examiner rejected Claims 1-9, 60, and 65-81 under 35 U.S.C. § 103(a) as being obvious over Schmutz et al. (U.S. Patent No. 3,389,139) in view of Tamminga et al. (2002). The Examiner asserts that Schmutz et al. teaches that N-desmethyloclozapine is suitable for the treatment of a psychotic condition. Applicants respectfully disagree. No where does Schmutz et al. disclose N-desmethyloclozapine. The Examiner alleges that Compound 11 in Schmutz et al. is N-desmethyloclozapine. However, this compound differs structurally from N-desmethyloclozapine in that it is an azepine instead of a diazepine and that it lacks the 8-chloro substituent present in N-desmethyloclozapine. The two compounds are depicted below:



Schmutz et al. Compound 11



N-desmethyloclozapine

There would be no reason based on Schmutz et al. for one of skill in the art to look to N-desmethyloclozapine for the treatment of psychosis. In fact, if one of skill in the art were looking for analogs of those compounds disclosed Schmutz et al. for antipsychotic therapy, they would

not investigate additional N-desmethyl analogs such as N-desmethylozapine because Schmutz et al. teaches away from such compounds. Schmutz et al. states that “[p]referred compounds within the range of this invention are those wherein the basic substituent in the 6-position is the 4-methyl-1-piperazinyl residue” (i.e., the N-methyl analogs instead of the N-desmethyl analogs). See *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (stating that when the prior art teaches away from an invention, it is more likely to be nonobvious). In addition, Schmutz et al. only discloses azepine compounds and does not direct one to investigate diazepine compounds. In *Takeda Chemical Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007), the Federal Circuit found that a claimed compound was not *prima facie* obvious over compounds disclosed in the prior art because the prior art did not direct one of skill in the art toward the claimed compound. The court noted that “[r]ather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation.” *Id.* The court further found that the prior art taught away from the closest prior art compound as being the likely lead for further investigation. See *id.* Similarly, in the instant case, Schmutz et al. does not identify predictable solutions for antipsychotic therapy and in fact teaches away from further research on N-desmethyl compounds. Nothing in Tamminga et al. further directs one of skill in the art towards N-desmethylozapine for antipsychotic therapy. Accordingly, Applicants respectfully submit that the cited art does not render the use of N-desmethylozapine to treat psychosis *prima facie* obvious. As such, Applicants request withdrawal of the rejections of Claims 1-9 and 59-81, all of which require administration of N-desmethylozapine to ameliorate one or more symptoms of psychosis.

In addition to the above reasons, Applicants respectfully submit that Claims 73-81 are not obvious over the cited art because they recite the treatment of cognitive impairment as well as the amelioration of one or more symptoms of psychosis. Nothing in Schmutz et al. or Tamminga et al. suggest that N-desmethylozapine is suitable for the treatment of cognitive impairment. Accordingly, for this additional reason, Applicants respectfully submit that Claims 73-81 are not obvious over the cited art.

Double Patenting

Application No.: 10/761,787
Filing Date: January 21, 2004

The Examiner provisionally rejected Claims 1-9, 60, and 65-81 for obviousness-type double patenting over claims 10-21 of copending Application No. 10/913,117; claims 1-6 and 19-29 of copending Application No. 11/098,892; claims 1-8 of copending Application No. 11/671,405; and claims 1-5 and 15 of copending Application No. 11/416,565. The Applicants request that this provisional rejection be held in abeyance until all pending claims in either the present application or one or more of the cited applications are otherwise allowable. See M.P.E.P. § 804(I)(B) ("The 'provisional' double patenting rejection should continue to be made by the examiner in each application...unless that 'provisional' double patenting rejection is the only rejection remaining in one of the applications. If the 'provisional' double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue").

Information Disclosure Statement

The Examiner did not initial the reference FR51 cited in the Information Disclosure Statement received July 19, 2004 due to an alleged invalid patent number. The Applicants note that regardless of the submission on July 19, 2004, the correct FR51 document was submitted in the Information Disclosure Statement received by the PTO on August 21, 2007 along with an English translation and the Examiner initialed the reference in that IDS as being fully considered.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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CONCLUSION

Applicants respectfully submit that by the foregoing amendments and remarks, they have overcome all pending rejections and request a timely issuance of a Notice of Allowance. The Examiner is invited to call the undersigned to resolve any remaining issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 5-6-08

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